



U.S. Department of Agriculture



Office of Inspector General
Northeast Region

Audit Report

Food Safety and Inspection Service Imported Meat And Poultry Equivalence Determinations Phase III

Report No. 24099-05-Hy
December 2003



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



DATE: December 29, 2003

REPLY TO

ATTN OF: 24099-05-Hy

SUBJECT: Imported Meat and Poultry Equivalence Determinations—Phase III

TO: Garry L. McKee
Administrator
Food Safety and Inspection Service

ATTN: Ronald F. Hicks
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

This report presents the results of the third phase of our audit of Food Safety and Inspection Service's (FSIS) controls to ensure that imported meat and poultry entering U.S. commerce is safe and wholesome. In this phase, we examined FSIS' controls for evaluating the equivalence of foreign countries' food safety systems. We concluded that FSIS implemented controls for documenting, reviewing, and approving the equivalence determinations made, which improved the agency's oversight of foreign food safety systems.

Your staff reviewed a draft of this report in November 2003, and in consultation with them, we determined that no exit conference was needed. The report contains no recommendations and a response by FSIS is not required. The report is final upon issuance.

We appreciate the cooperation and assistance provided to Office of Inspector General staff during this review.

//s//

RICHARD D. LONG
Assistant Inspector General
for Audit

Executive Summary

Food Safety and Inspection Service Imported Meat and Poultry Equivalence Determinations Phase III (Audit Report No. 24099-05-Hy)

Results in Brief

This report presents the results of the third phase of our audit of the Food Safety and Inspection Service's (FSIS) controls to ensure that imported meat and poultry entering U.S. commerce is safe and wholesome. In this phase, we examined FSIS' controls for evaluating the equivalence of foreign countries' food safety systems. In the first phase¹ of our audit, we evaluated FSIS' controls at the management level for ensuring the safety of imported meat and poultry. During the second phase,² we examined FSIS' controls over the import reinspection process.

FSIS is to fulfill its responsibilities for ensuring that imported meat and poultry in the U.S. marketplace is safe, wholesome, unadulterated, and properly labeled by: (1) determining if foreign countries and their establishments have implemented food safety systems and inspection requirements equivalent to those of the United States, and (2) reinspecting imported meat and poultry products from these countries, through random sampling of shipments. The reinspection process is designed to be a check on the effectiveness of foreign countries' inspection systems.

We examined FSIS' controls for evaluating the equivalency of foreign country's Hazard Analysis and Critical Control Point (HACCP) and *Salmonella* testing requirements. We also evaluated FSIS' procedures for making the initial determination of a foreign country's equivalency and reviewed FSIS' actions in response to our Phase I recommendations.

To accomplish these objectives, we focused on operations and decisions made from December 1999 through June 2003. We evaluated the equivalence determinations made for 32 of the 37 countries already approved to export product to the United States. These countries have exported, on average, over 3.5 billion pounds of meat and poultry products annually to the United States since 1999. No new countries have been approved to export product to the United States since our prior report was issued in June 2000; however, two initial equivalence determinations were close to being finalized. Accordingly, we evaluated FSIS' May 2002 determinations to allow: (1) Slovakia to export meat products to the United States, and (2) New Zealand to use an alternative generic *E. coli* testing program for bobby calves (veal).

We concluded that FSIS implemented controls for documenting, reviewing, and approving the equivalence determinations made, which improved the

¹ Audit Report No. 24099-03-Hy, Food Safety and Inspection Service Imported Meat and Poultry Inspection Process Phase I, issued June 21, 2000.

² Audit Report No. 24099-04-Hy, Food Safety and Inspection Service Imported Meat and Poultry Reinspection Process Phase II, issued February 25, 2003.

agency's oversight of foreign food safety systems. These controls were followed in FSIS' determinations of the equivalence of the HACCP and *Salmonella* testing requirements for the 32 countries we selected for review. We also found that these procedures were followed when FSIS evaluated the equivalence of the residue control programs for the 33 countries already approved to export product to the United States. Finally, the controls were followed as FSIS made its initial equivalence determinations for Slovakia's meat inspection program and New Zealand's alternative generic *E. coli* testing program.

We found that FSIS implemented the agreed upon corrective actions for the 17 recommendations in our June 2000 audit report (see exhibit A). Accordingly, we are making no recommendations to FSIS.

Abbreviations Used in This Report

Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
CFR	Code of Federal Regulations
<i>E. coli</i>	Escherichia coli
FSIS	Food Safety and Inspection Service
GPRA	Government Performance and Results Act
HACCP	Hazard Analysis and Critical Control Point
SSOP	Sanitation Standard Operating Procedures

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Background and Objectives

Background

The Federal Meat Inspection Act and the Poultry Products Inspection Act require foreign countries that export meat and poultry products to the United States to establish and maintain systems that are equivalent to the U.S. inspection system. Meat and poultry imported into the United States must originate in countries and plants approved to export to the United States. FSIS is responsible for monitoring foreign countries and exporters to ensure the countries' food safety systems are acceptable by U.S. standards and that exporters are certified as meeting those standards. FSIS is also responsible for reinspecting imported meat and poultry products at ports of entry to ensure that only safe, wholesome, unadulterated, and properly labeled products enter U.S. commerce. Regulations governing FSIS operations are codified in Title 9, Code of Federal Regulations (CFR), Chapter III.

A total of 37 countries are currently approved to export meat and poultry products to the United States. Three of the approved countries either had no establishments exporting product to the United States or had suspended trade with the United States. The approved countries have exported, on average, over 3.5 billion pounds of meat and poultry products annually to the United States since 1999. No new countries have been approved to export product to the United States since our prior audit report that was issued in June 2000.

FSIS administers its imported meat and poultry program primarily through the Office of International Affairs, which reviews food safety requirements imposed by foreign governments and inspects imported meat and poultry products, and the Office of Program Evaluation, Enforcement, and Review, which inspects overseas plants. Within the Office of International Affairs, the International Equivalence Staff is responsible for formulating policies and determining a foreign country's eligibility to export meat and poultry products to the United States. These review and inspection activities form the basis of FSIS' determinations of whether a country's inspection systems are equivalent to U.S. standards.

Food safety equivalence evaluations are based on provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures (Agreement), which became effective in January 1995. Prior to the Agreement, FSIS focused on individual plants and evaluated whether foreign food safety systems were "at least equal to" the U.S. system. The principle underlying FSIS' current import inspection activities is the "systems approach," which evaluates the equivalence of the inspection system controls of each country.

In fiscal year 1996, FSIS published the final rule for the pathogen reduction and HACCP systems. Under these systems, a country's status as having controls and performance standards equivalent to those in the United States are determined in four areas.

- HACCP. All plants must develop, adopt, and implement a HACCP plan for each of their processes. Under HACCP, plants identify critical control points during their processes where hazards such as microbial contamination can occur, establish controls to prevent or reduce those hazards, and maintain records documenting that controls are working as intended.
- Mandatory Generic Escherichia coli (*E. coli*) testing in slaughter plants. All meat and poultry slaughter plants are required to conduct microbial testing of carcasses for generic *E. coli* as an indicator of the adequacy of the plant's control over fecal contamination.
- Pathogen reduction performance standards for *Salmonella*. Slaughter plants and plants producing raw ground products are required to ensure that their *Salmonella* contamination rate is below the current national baseline incidence.
- Sanitation Standard Operating Procedures (SSOP). All plants were required to implement plant-specific operating procedures for sanitation to ensure they were meeting their responsibility to keep their facilities and equipment clean.

Countries that had food safety systems "at least equal to" the United States were allowed to continue to export meat and poultry to this country while FSIS evaluated the equivalence of these systems under the pathogen reduction and HACCP standards. FSIS did not suspend trade with exporting countries while this process was underway. A total of 37 countries were approved under the "equal to" system. The burden for demonstrating equivalence rests with the exporting country and the importing country is free to set any level of protection it deems appropriate to control or eliminate a food safety hazard.

Before a foreign country can initially export meat or poultry to the United States, it must apply for a determination of equivalency. The application must contain enough technical and scientific evidence for FSIS to determine that the country's sanitary measures, oversight, and enforcement are equivalent to the U.S. system. This evaluation is to consist of a document review and an onsite equivalency verification review. The initial equivalence determination for a new trading partner is subject to notice and comment rule making when the country is listed in the CFR as eligible to export to the United States.

A document review is an evaluation of laws, regulations, directives and other written material used by the foreign country to operate its inspection program. FSIS will evaluate the country's inspection system in five risk areas, which include controls over animal diseases, sanitation, enforcement, residue, and slaughter and processing. If the document review finds the country's system satisfactory, FSIS will conduct an onsite equivalency verification review to evaluate the foreign country's oversight program and practices, and to determine whether system controls are operating as represented to FSIS.

After a country is determined to have an equivalent system and is eligible to export to the United States, FSIS will rely on the country to carry out daily inspections. However, FSIS will monitor the country's activities. Besides randomly sampling meat and poultry products for reinspection as they enter the United States, FSIS will conduct onsite reviews of the country's inspection system to ensure that its procedures and standards remain equivalent. Reviewers will visit certified plants and focus on the five areas of risk (i.e., animal disease, sanitation, enforcement, residue, and slaughter and processing). These reviews are generally conducted annually.

During the first phase of our audit, we evaluated FSIS' controls at the management level for ensuring that imported meat and poultry entering the U.S. consumer channels was safe and wholesome. Overall, we found that FSIS' management control over the import inspection program needed to be enhanced. This included enhancement of FSIS' documentation of approved foreign food safety systems. In addition, we concluded that the import reinspection process did not ensure that ineligible importers were properly identified and that recognized pathogen violations were responded to promptly. These results were reported in Audit Report No. 24099-03-Hy, Food Safety and Inspection Service Imported Meat and Poultry Inspection Process Phase I, issued June 21, 2000.

During the second phase of our audit, we examined FSIS' controls over the import reinspection process, which included visits to import inspection houses. We also reviewed FSIS' action in response to 18 of the 35 Phase I recommendations. Overall, we concluded that FSIS had made minimal progress toward establishing an effective import reinspection process, even though the agency agreed to do so in response to our June 2000 audit report. FSIS' management information system contained weaknesses that raised concerns about the safety of imported products. Finally, FSIS needed to clarify agency authority over imported product. These results were reported in Audit Report No. 24099-04-Hy, Food Safety and Inspection Service Imported Meat and Poultry Reinspection Process Phase II, issued February 25, 2003.

Objectives

The objective of our review was to evaluate FSIS' equivalency determinations for HACCP and *Salmonella* for countries already approved to export products to the United States and FSIS' procedures for making the initial determination of a foreign country's eligibility to export products to the United States. We also determined the extent to which FSIS implemented recommendations related to equivalence determinations from our June 2000 audit report and evaluated the applicable performance measures and controls governing the validity of data FSIS reported in the Government Performance and Results Act (GPRA) annual plan.

To accomplish these objectives, we focused on operations and decisions made by FSIS from December 1999 through June 2003. We evaluated the equivalence determinations made for 32 of the 37 countries already approved to export product to the United States. We also evaluated FSIS' process for making initial equivalence determinations by reviewing the May 2002 determination to allow the country of Slovakia to export meat products to the United States. Finally, we reviewed FSIS' May 2002 determination to allow New Zealand to use an alternative generic *E. coli* testing program for bobby calves.

General Comments

In response to our June 2000 audit report, FSIS implemented controls for documenting, reviewing, and approving the equivalence of foreign countries' food safety systems. These controls included such things as a formalized process for making the equivalence determination and using technical subject matter experts. We found that these controls were followed in the agency's determinations of the equivalence of the HACCP and *Salmonella* testing requirements for 32 of the 37 countries already approved to export product to the United States. These countries have exported, on average, over 3.5 billion pounds of meat and poultry products annually to the United States since 1999. See Exhibit A for a summary of FSIS' actions to address 17 of the 35 recommendations made in our June 2000 audit report.

We also found that FSIS implemented the control procedures when evaluating the equivalence of the residue control programs for 33 countries. Based on an initial assessment of the residue control programs, FSIS concluded that each country had an adequate residue control program. FSIS is in the process of finalizing its review for all countries. This review has been completed for the countries that traditionally import the most product into the United States (i.e., Canada, Australia, New Zealand, and Denmark).

Finally, we found that established procedures were followed when FSIS determined in May 2002, that Slovakia should be allowed to export meat products to the United States and New Zealand should be allowed to use an alternative generic *E. coli* testing program for bobby calves.

FSIS' implementation of the controls to document, review, and approve equivalence determinations strengthens the data the agency reports in its annual performance report required by GPRA. Two of the indicators that FSIS uses to assess its performance are to determine: (1) the number of countries meeting the HACCP equivalency standards and exporting to the United States, and (2) the number of foreign program reviews conducted to ensure international equivalency and maintain export eligibility to the United States.

Scope and Methodology

To evaluate FSIS' equivalency determinations for HACCP and *Salmonella*, we focused our review on operations and decisions made from December 1999 through June 2003. FSIS announced its determinations regarding the equivalence of foreign food safety systems based on pathogen reduction and HACCP requirements at a public meeting on December 14, 1999. We evaluated the determinations made for 32 of the 37 countries already approved to export product to the United States.

We evaluated FSIS' procedures for making the initial determinations of equivalency by reviewing the May 2002 determination to allow the country of Slovakia to export meat products to the United States. We also reviewed the May 2002 determination to allow New Zealand to use an alternative generic *E. coli* testing program for bobby calves. These were the determinations that were closest to being finalized since our last audit.³

We performed work at FSIS' Headquarters in Washington, D.C. and the Technical Service Center in Omaha, Nebraska. To fulfill our objectives, we discussed current operations with FSIS staff and reviewed supporting documentation. We concentrated on the responsibilities of the International Equivalence Staff and the Foreign Review Staff. The International Equivalence Staff is within the Office of International Affairs. The Foreign Review Staff is within the Office of Program Evaluation, Enforcement, and Review. Our review included analysis of records and other documents and discussions with responsible officials to determine if agency responsibilities are being carried out as intended by regulation.

We conducted our work between August 2000 and August 2003 in accordance with generally accepted Government auditing standards.

³ Audit Report No. 24099-03-Hy, Food Safety and Inspection Service Imported Meat and Poultry Inspection Process Phase I, issued June 21, 2000.

Exhibit A – Status of Recommendations Made in our June 2000 Audit Report

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The following table shows the actions taken by FSIS to address 17 of the 35 recommendations made in our June 2000 audit report, related to the equivalence determination portion of FSIS' import inspection operations. (The remaining 18 recommendations were evaluated as part of our review of the import reinspection process, Audit Report No. 24099-04-Hy, FSIS Imported Meat and Poultry Reinspection Process Phase II, issued February 25, 2003.)

Phase I Report Recommendations	Agency Action
8. Prior to the onsite review, ensure that the Technical Service Center (TSC) reviewers are provided with all information necessary to verify data provided by foreign countries for equivalence determinations.	Through procedures developed and implemented in August 2002, FSIS standardized the type of documentation to be maintained in the TSC files. This documentation included such items as foreign country cables, product complaints, foreign plant listings and delistments, general correspondence, review plans and itineraries, review reports, review notes, checklists, summaries, and enforcement actions. We validated the procedures were implemented by reviewing a sample of files maintained by the foreign review staff at the TSC.
10. With the help of technical subject-matter experts, develop and implement comprehensive guidelines as a means of ensuring propriety and consistency in decisions involving equivalency determinations.	FSIS developed and implemented these comprehensive written guidelines. They are documented as part of FSIS' Equivalence Management Controls. ⁴ We confirmed that FSIS consistently used these guidelines for making ongoing equivalence determinations for HACCP and <i>Salmonella</i> testing requirements and for making initial equivalence determinations. Through a review of FSIS' foreign country review reports, we found that FSIS developed standardized methods for collecting and analyzing information about the ongoing equivalence of foreign countries HACCP and <i>Salmonella</i> testing requirements.

⁴ FSIS' Equivalence Management Controls was first issued in January 2001. The procedures were updated in September 2001 and other updates will be made, as necessary.

Phase I Report Recommendations	Agency Action
<p>11. Develop written criteria and procedures for suspending the eligibility of exporting countries that do not provide sufficient documentation to support their continuing compliance with U.S. equivalency standards or are found to be in noncompliance based on the results of an onsite equivalency review.</p>	<p>FSIS' Office of International Affairs developed and implemented these procedures in March 2003. They are a part of FSIS' Equivalence Management Controls. We verified that the procedures were in use through review of files and information maintained by the International Equivalence Staff.</p>
<p>12. Develop written procedures, which ensure comprehensive evaluations of foreign countries' alternative import inspection methods, and require the analysis of these systems be documented, as well as the decisions reached.</p>	<p>FSIS developed and implemented these procedures as part of its Equivalence Management Controls. Through review of files maintained by the International Equivalence Staff, we confirmed that equivalence decision files contain: 1) FSIS correspondence with foreign countries; 2) Foreign country submissions (translated and in the originating language); 3) Summary reviews of submissions; 4) Summary of meetings and teleconferences with foreign officials; 5) Summary of reviews by subject-matter experts; 6) Documentation of equivalence criteria; 7) Summary of FSIS formal reviews and approvals; and 8) Decision memorandum of the equivalence determinations.</p>

Phase I Report Recommendations	Agency Action
23. Establish procedures to ensure that all residue documents submitted by foreign countries are received, reviewed, and analyzed based on requirements outlined in regulations.	<p>FSIS proposed an alternative action in response to Recommendation Nos. 23 through 26, which OIG accepted for management decision. FSIS developed and implemented procedures for reviewing foreign countries' residue control programs, which included an initial determination based on the review of documents followed by an indepth review of program operations in the foreign country. FSIS also developed and implemented procedures for taking appropriate actions when violations are detected.</p> <p>Through review of FSIS' documentation of its review of 33 foreign countries' residue control programs, we verified that FSIS completed its initial determination by April 2001. Based on this, FSIS concluded that each country had an adequate residue control program. FSIS is in the process of finalizing its reviews of each country's submission. The final determinations are documented in a decision memorandum that is prepared by the Equivalence Staff Officer, approved by the Director of the International Equivalence Staff, and concurred with by the Deputy Assistant Administrator for International Affairs. These determinations have been completed for the countries that traditionally import the most product into the United States (i.e., Canada, Australia, New Zealand, and Denmark).</p>
24. Obtain the residue test plans not submitted since 1998 to determine if the foreign countries have residue control standards equivalent to the United States.	
25. Obtain and analyze the residue test plan results not submitted since 1998 to determine the adequacy of foreign countries' adherence to their residue test plans.	
26. Develop procedures to ensure that (a) a review of residues identified by the exporting country's meat inspection authorities or by FSIS as potential contaminants are included as part of the Technical Service Center onsite equivalency reviews, and (b) appropriate action is taken in those instances where the plans are inadequate, the results vary from the plans, or violations are detected.	

Phase I Report Recommendations	Agency Action
27. Develop procedures that require the participation of technical subject-matter experts, as appropriate, in equivalency determinations, and document the experts' participation, analyses, and conclusions.	FSIS developed formal procedures for participation of technical subject-matter experts, as appropriate, in equivalence determinations. These procedures are part of FSIS' Equivalence Management Controls. See also FSIS' actions in response to Recommendation No. 10.
28. Document and implement a system of internal controls to ensure the adequacy and support for foreign equivalency determinations. This should include a formal review and approval process for the equivalence determinations made.	FSIS implemented this system of controls as part of the Equivalence Management Controls. The equivalence decision files contain the sections listed in response to Recommendation No. 12.
29. Develop a management control process and procedures to ensure equivalence decisions are adequately documented. The procedures should require that files contain supporting evidence, including detailed analysis of information received and reviewed, resolution of issues raised during the review process, and conclusions reached.	FSIS agreed that equivalence decisions should be adequately documented and that the files must be complete. Therefore, FSIS instituted the same measures described in response to Recommendation No. 28.
30. Establish a time-phased plan to expedite the process for determining equivalency.	FSIS implemented time-phased plans for future equivalence determinations, which are documented as part of the agency's Equivalence Management Controls.
31. Ensure that onsite audits for current trading partners are conducted at least annually.	FSIS incorporated this requirement as part of its Equivalence Management Controls.
32. For current trading partners, develop and implement a policy for onsite verifications of changes in the requirements for foreign inspection systems.	FSIS revised its onsite review procedures to verify any changes in requirements. This is documented as part of FSIS Equivalence Management Controls.

Phase I Report Recommendations	Agency Action
33. Clarify the regulations regarding FSIS' procedures for determining equivalence for current trading partners, taking into consideration major changes such as HACCP and pathogen reduction requirements.	FSIS proposed an alternative action to Recommendation No. 33, which OIG accepted for management decision. FSIS revised its onsite review procedures to ensure that major changes such as HACCP and pathogen reduction requirements are considered when determining the equivalence for current trading partners. These revised procedures are part of FSIS' Equivalence Management Controls. FSIS documents this information as referenced in response to Recommendation No. 12.
34. Ensure that reporting and evidence standards developed for equivalency verification reviews provide for appropriate documentation of all areas required to be reviewed by regulation.	FSIS standardized the format of its review reports to address the following five risk areas: 1) animal disease controls; 2) sanitation controls; 3) enforcement controls; 4) slaughter and processing controls; and 5) residue controls. These five risk areas cover all of the FSIS regulatory requirements for countries that export to the United States.
35. Develop procedures for timely completing reports documenting reviews of foreign inspection systems.	FSIS developed and implemented procedures, which set timeframes for drafting the report, issuing the report to the foreign country, and obtaining the foreign country's response. The procedures are documented as part of FSIS' Equivalence Management Controls.